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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,095	03/29/2001	Ming-Hui Wei	CL001202	2541
7590 08/31/2005 CELERA GENOMICS CORPORATION 45 West Gude Dr. C2-4#20 Rockville, MD 20850			EXAMINER WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/820,095	Applicant(s) WEI ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 8, 9 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 4, 8, 9, 24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

Applicant's traversal filed on 8/10/05 is acknowledged and considered by the examiner.

Claims 4, 8, 9, 24-29 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/12/05 was filed after the mailing date of the office action on 5/10/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The examiner has considered the European Search Report, but the examiner will not initial the report on the IDS because the report is not considered to be a published document.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The phrase “a nucleotide sequence that encodes a polypeptide having an amino acid sequence comprising SEQ ID NO: 2 in instant claim 4(a)” reads on a nucleotide sequence encoding a polypeptide of any length of SEQ ID NO: 2.

The phrase “an amino acids sequence comprising SEQ ID NO: 2” in instant claim 24 reads on an amino acid of any length of SEQ ID NO: 2.

Claims 4, 8, 9, 24, and 27-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Takino et al. (WO 98/42835). Takino et al. teach a nucleotide sequence encoding the entirety of or a portion of the amino acid sequence represented by SEQ ID NO: 3 (abstract and column 2 of US 6,255,472, which is the English equivalent of WO 98/42835). SEQ ID NO: 3 is 99.0% identical to SEQ ID NO: 2 of the instant application. Takino et al. teach the limitation in instant claims 8 and 27-29 (column 5, which is the English equivalent of WO 98/42835). Takino et al. teach the limitation in instant claim 9 (column 5, which is the English equivalent of WO 98/42835). Takino teaches a method of producing a polypeptide using the host cell (column 5, which is the English equivalent of WO 98/42835).

Applicant's arguments filed 8/10/05 have been fully considered but they are not persuasive.

In response to applicant's argument that compared to SEQ ID NO: 2 of the instant invention SEQ ID NO: 3 of Takino's contains an insertion of 26 additional amino acid residues and contains an insertion that is located within (as opposed to if the additional amino acid segment was located at the end of the instant SEQ ID NO: 2), the argument is not found persuasive because the phrase reads on any polypeptide having SEQ ID NO: 2, including polypeptides having additional amino acids contain within/at the beginning/ at the end of the amino acid sequence.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 8, and 28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Takino et al. (WO 98/42835) taken with Bard et al. (US 5,714,381).

Takino et al. teach a nucleotide sequence encoding the entirety of or a portion of the amino acid sequence represented by SEQ ID NO: 3 (abstract and column 2 of US 6,255,472,

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which is the English equivalent of WO 98/42835). SEQ ID NO: 3 is 99.0% identical to SEQ ID NO: 2 of the instant application. Takino et al. teach a vector (plasmid) comprising the nucleotide sequence (column 5, which is the English equivalent of WO 98/42835). However, Takino et al. do not specifically teach a virus (e.g., bacteriophage) comprising the nucleotide sequence.

However, at the time the invention was made, Bard et al. teach inserting a nucleotide sequence into a virus such as bacteriophage (column 10). Bard further teaches that nucleic acid sequences are inserted into vectors by methods well known to those of ordinary skill in the art (column 10).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Takino taken with Bard, namely to produce a virus (bacteriophage) comprising the nucleotide sequence. One of ordinary skill in the art would have been motivated, as a matter of designer's choice, to combine the teachings to produce the bacteriophage for expressing the nucleotide sequence in bacteria and because Bard teaches that inserting a nucleotide sequence into a vector (bacteriophage) is well known to one of ordinary skill in the art.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 8/10/05 have been fully considered but they are not persuasive because the argument is based on the above discussion in response to the 102(b) rejection. The argument was already addressed under the 102(b) rejection.

Conclusion

Instant Claims 25 and 26 are in condition for allowance because the instant claims are free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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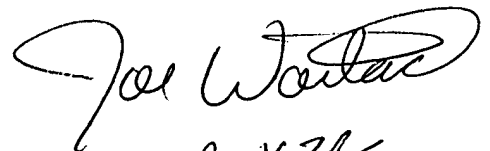
Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635


AW/16/28